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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/783,734	01/16/1997	JEFFREY M. FRIEDMAN	600-1-162CP2	1933

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EXAMINER

O HARA, EILEEN B

ART UNIT PAPER NUMBER

1646

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/783,734

Applicant(s)

FRIEDMAN ET AL.

Examiner

Eileen O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-31 and 67-72 is/are pending in the application.
- 4a) Of the above claim(s) 67-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to where
- 8) ☒ Claim(s) 29-31 and 67-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 1997 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

3.05

DETAILED ACTION

1. Claims 29-31 and 67-73 are pending in the instant application. Claims 29-31, 67-70 and 73 have been amended as requested by Applicant in the Paper filed May 6, 2005.

Claims 67-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 29-31 are under examination.

Withdrawn Objections and Rejections

2. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

New Rejections or Objections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3.1 Claims 29-30 are indefinite because they are drawn to an isolated oligonucleotide "specifically" hybridizable under stringent conditions, corresponding to 40% formamide with 5X or 6X SSC. Because the claims recite "**corresponding** to 40% formamide with 5X or 6X SSC", they read on other stringency conditions, and the resulting claims do not clearly set forth the metes and bounds of the patent protection desired. Additionally, there are no temperatures or wash conditions recited, which are important in defining the hybridization conditions.

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3.2 Claim 30 is indefinite because it recites "consisting essentially of amino acids 28-805 of SEQ ID NO: 10, and the phrase "consisting essentially of" refers to compositions, so it is not clear how it pertains to a protein.

3.3 Claim 31 is indefinite because it is drawn to an oligonucleotide specifically hybridizable to the nucleic acid "having *a* nucleotide sequence" corresponding to or complementary to the DNA sequence set forth in SEQ ID NO: 9. Because SEQ ID NO: 9 is a defined sequence, the phrase "having *a* nucleotide sequence" is indefinite, because it indicates that there is more than one sequence. The rejection would be withdrawn if "having *a* nucleotide sequence" were replace with "having *the* nucleotide sequence".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4.1 Claim 29 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA molecule encoding on expression a soluble leptin receptor which is a DNA molecule of SEQ ID NO: 9, it does not reasonably provide enablement for an isolated DNA molecule encoding on expression a soluble leptin receptor which is the complement of SEQ ID NO: 9. The instant specification on teaches that the nucleic acid sequence of SEQ ID NO: 9 encodes the leptin receptor of SEQ ID NO: 10. However, claim 29 in the preamble recites:

"...to the nucleic acid molecule encoding on expression a soluble leptin receptor polypeptide selected from the group consisting of:

- a. a DNA molecule of SEQ ID NO: 9;
- b. a DNA molecule complementary to the DNA molecule defined in (a);"

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However, the complement of SEQ ID NO: 9 would not encode the leptin receptor. Part (c) of claim 29 also encompasses a DNA that encodes a leptin receptor encoded by the complement of the encoding nucleic acid.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 29 and 30 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants traverse the rejection on page 6 of the response, and submit that the Specification provides a precise definition of the oligonucleotides claimed, and that the claims as presented are fully enabled under 35 U.S.C. 112, first paragraph, and meet the written description requirements, setting out a precise definition of the claimed oligonucleotides.

Applicants' arguments have been fully considered but are not deemed persuasive. Claims 29 and 30, each encompass a specific nucleic acid sequence encoding a specific polypeptide, *or allelic variants thereof*, which would not have the same sequences. No allelic variants are disclosed in the specification.

Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 29-31 remain rejected under 35 U.S.C. 102(e) as being anticipated by Tartaglia et al., US Patent No. 6,506,877, filing date Dec. 28, 1995.

Applicants traverse the rejection on pages 6-7 of the response and assert that Tartaglia et al. does not teach or anticipate the soluble leptin receptor of the instant invention as claimed by Applicants, particularly in as much as the C-terminal sequence of this soluble receptor diverges after His⁷⁹⁶. Applicants assert that the pending claims are directed to oligonucleotides specifically hybridizable to nucleic acids encoding the soluble leptin receptors OB-Re (SEQ ID NO: 10) or amino acids 28-805 of SEQ ID NO: 10, and point to Example 3 at pages 80-82 and in TABLE 1, which contemplates and describes oligonucleotides (PCR primer probes) specifically hybridizable to species variants of OB-R, such oligonucleotides useful to identify unique splice variants, and that the specification further teaches the sequence of the OB-Re species variant soluble receptor.

Applicants' arguments have been fully considered but are not deemed persuasive. Because claims 29-31 are drawn to oligonucleotides hybridizable to the recited nucleic acid molecules, not the soluble receptor itself, Tartaglia et al. anticipates the claims. The instant specification at the paragraph bridging pages 37-38 teaches that preferably a minimum length for a hybridizable nucleic acid is at least about 10 nucleotides, more preferably at least about 15 nucleotides, and most preferably the length is at least about 20 nucleotides. There is no

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limitation in the claims that the oligonucleotide span the region between His⁷⁹⁶ and Asp⁸⁰⁵.

Therefore, the vast majority of oligonucleotides as claimed would hybridize to the nucleotide sequence of Tartaglia et al., in the region from nucleotides 44-2388 of SEQ ID NO: 9, which is identical to the sequence of Tartaglia except for one base change (the open reading frame encoding the polypeptide of SEQ ID NO: 10 is nucleotides 44-2457).

It is believed that all pertinent arguments have been answered.

Conclusion

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (571) 272-0829.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner



**EILEEN B. O'HARA
PATENT EXAMINER**